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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/724,839

12/01/2003

Gregory Dean Sunvold

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27752 7590 12/02/2010
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EXAMINER

OLSON, ERIC

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

12/02/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/724,839 | Applicant(s) SUNVOLD ET AL. | |
| | Examiner ERIC S. OLSON | Art Unit 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33,34,42,47 and 55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33,34,42,47 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

This office action is a response to applicant's communication submitted October 8, 2010 wherein claim 32 is amended. This application was filed December 1, 2003 and makes no priority claims.

Claims 32, 34, 42, 47, and 55 are pending in this application.

Claims 32, 34, 42, 47, and 55 as amended are examined on the merits herein.

Applicant's amendment, submitted 8, 2010, with respect to the rejection of instant claims 32, 34, 42, 47, and 55 under 35 USC 103(a) for being obvious over Baillon et al. in view of Kaplan et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to additionally require the presence of calcium. Therefore the rejection is withdrawn.

Abstract

Applicant's amendment to the abstract is acknowledged. The amendment is persuasive to remove the objection to the abstract as the amended abstract is a single paragraph.

Applicant's amendment necessitates the following new grounds of rejection:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32, 34, 42, 47, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baillon et al. (US pre-grant publication 2003/0195166, of record in previous action, also published as PCT international publication WO01/65949, of record in previous action) in view of Kaplan et al. (Reference of record in previous action) in view of Abene et al. (US patent 6669975, cited in PTO-892)

Baillon et al. discloses the use of a non-digestible carbohydrate for the treatment of pathogenic bacteria in the large intestine of a pet animal. (p. 1 paragraph 0012) Non-digestible carbohydrates include fructooligosaccharide such as kestose, nystose, and beta-fructofuranosylnystose, as well as beet pulp. (p. 1 paragraph 0014 - p. 2 paragraph 0016) In a preferred embodiment the non-digestible carbohydrate is a prebiotic which selectively stimulates the growth and/or activity of beneficial bacteria such as

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bifidobacteria or lactobacilli. (p. 2 paragraphs 0020-0021) The animal treated by this method is preferably a cat or a dog. (p. 2 paragraph 0025) The composition is preferably a cat or dog food such as a kibble (p. 2 paragraph 0026) having 20-30% protein, 10-20% fat, and the remainder (50-70%) being carbohydrate including dietary fiber and ash. (p. 3 paragraph 0028) The oligosaccharide is preferably included at an amount of from 0.1-2%. (p. 3 paragraph 0030) The pet food may be administered as 100% of the diet, meaning that it is nutritionally balanced. (p. 3 paragraph 0036) If it is administered as the sole food source, the composition will necessarily be administered at least once daily. Regarding claims 34 and 47, administering the same composition as the claims to the same subjects will necessarily be expected to produce the same result. Also, regarding "improving physical activity performance," Baillon et al. discloses in p. 2 paragraph 0024 that the claimed compositions can be used to treat *Campylobacter jejuni* infection which can cause diarrhea, tenesmus, vomiting, anorexia, depression, and inflammatory intestinal disease. These conditions would reasonably be expected to reduce the ability of a cat or dog to perform physical activity. Therefore treating *Campylobacter jejuni* infection is reasonably expected to improve a sick animal's ability to perform physical activity. Baillon et al. does not disclose a method comprising administering a composition having the specific claimed ratio of kestose to nystose to fructofuranosyl-nystose, or one comprising less than 1% of calcium.

Kaplan et al. discloses a study of the bacterial fermentation properties of a commercial fructooligosaccharide mixture comprising 32% GF₂ (kestose), 53.6% GF₃ (nystose), and 9.8% GF₄. (fructofuranosyl-nystose). (p. 2682, right column paragraphs

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2-3) The fructooligosaccharide mixture was found to support the growth of various beneficial *Lactobacillus* and *Bifidobacterium* species. (p. 2683, left column table 1)

Abene et al. discloses that the required amount of calcium of the Association of American Feed Control Officials (AAFCO) profile for dog food requires a minimum of 0.6% calcium and a maximum of 2.5% calcium for an adult maintenance diet. (column 2 lines 5-45)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the commercial fructooligosaccharide mixture studied by Kaplan et al. in the compositions and methods described by Baillon et al. in an amount of 0.2%. One of ordinary skill in the art would have been motivated to use this composition because it is disclosed by Kaplan et al. to be useful for the desired purpose for which Baillon et al. uses the fructooligosaccharide, namely promoting the growth of beneficial lactic acid bacteria such as *Lactobaccilli* and *Bifidobacteria*. One of ordinary skill in the art would reasonably have expected success because substituting one known prior art composition with another that is known to have the same effect is well within the ordinary and routine level of skill in the art.

It would furthermore have been obvious to include under 1%, for example 0.6-1% of calcium in the food composition in view of the required AAFCO nutrient profile disclosed by Abene et al. for dog food. When the claimed range overlaps with the prior art, a *prima facie* case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1].

Therefore the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment necessitated this new ground of rejection, the rejection is made **FINAL**.

Claims 32, 34, 42, 47, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baillon et al. (US pre-grant publication 2003/0195166, of record in previous action, also published as PCT international publication WO01/65949, of record in previous action) in view of Kaplan et al. (Reference of record in previous action) in view of Shields et al. (US patent 6156355, cited in PTO-892)

Baillon et al. discloses the use of a non-digestible carbohydrate for the treatment of pathogenic bacteria in the large intestine of a pet animal. (p. 1 paragraph 0012) Non-digestible carbohydrates include fructooligosaccharide such as kestose, nystose, and beta-fructofuranosylnystose, as well as beet pulp. (p. 1 paragraph 0014 - p. 2 paragraph 0016) In a preferred embodiment the non-digestible carbohydrate is a prebiotic which selectively stimulates the growth and/or activity of beneficial bacteria such as bifidobacteria or lactobacilli. (p. 2 paragraphs 0020-0021) The animal treated by this method is preferably a cat or a dog. (p. 2 paragraph 0025) The composition is preferably a cat or dog food such as a kibble (p. 2 paragraph 0026) having 20-30% protein, 10-20% fat, and the remainder (50-70%) being carbohydrate including dietary fiber and ash. (p. 3 paragraph 0028) The oligosaccharide is preferably included at an amount of from 0.1-2%. (p. 3 paragraph 0030) The pet food may be administered as 100% of the diet, meaning that it is nutritionally balanced. (p. 3 paragraph 0036) If it is

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administered as the sole food source, the composition will necessarily be administered at least once daily. Regarding claims 34 and 47, administering the same composition as the claims to the same subjects will necessarily be expected to produce the same result. Also, regarding "improving physical activity performance," Baillon et al. discloses in p. 2 paragraph 0024 that the claimed compositions can be used to treat *Campylobacter jejuni* infection which can cause diarrhea, tenesmus, vomiting, anorexia, depression, and inflammatory intestinal disease. These conditions would reasonably be expected to reduce the ability of a cat or dog to perform physical activity. Therefore treating *Campylobacter jejuni* infection is reasonably expected to improve a sick animal's ability to perform physical activity. Baillon et al. does not disclose a method comprising administering a composition having the specific claimed ratio of kestose to nystose to fructofuranosyl-nystose, or one comprising less than 1% of calcium.

Kaplan et al. discloses a study of the bacterial fermentation properties of a commercial fructooligosaccharide mixture comprising 32% GF₂ (kestose), 53.6% GF₃ (nystose), and 9.8% GF₄. (fructofuranosyl-nystose). (p. 2682, right column paragraphs 2-3) The fructooligosaccharide mixture was found to support the growth of various beneficial *Lactobacillus* and *Bifidobacterium* species. (p. 2683, left column table 1)

Shields et al. discloses various dog food formulations intended for specific breeds of dog. (column 3 lines 30-33) One of these formulations, intended for sporting dogs, contains a maximum of 1% calcium, as well as minimum 25% protein and 15% fat, which fall within the limits recited in the instant claims. (column 25 lines 10-20)

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It would have been obvious to one of ordinary skill in the art at the time of the invention to use the commercial fructooligosaccharide mixture studied by Kaplan et al. in the compositions and methods described by Baillon et al. in an amount of 0.2%. One of ordinary skill in the art would have been motivated to use this composition because it is disclosed by Kaplan et al. to be useful for the desired purpose for which Baillon et al. uses the fructooligosaccharide, namely promoting the growth of beneficial lactic acid bacteria such as *Lactobacilli* and *Bifidobacteria*. One of ordinary skill in the art would reasonably have expected success because substituting one known prior art composition with another that is known to have the same effect is well within the ordinary and routine level of skill in the art.

It would furthermore have been obvious to include under 1% calcium in the food composition as described by Shields et al. One of ordinary skill in the art would have been motivated to do so in order to adapt the composition for use by sporting dogs as described by Shields. One of ordinary skill in the art would reasonably have expected success because the amounts of other nutrients described in this composition by Shields et al. are compatible with the amounts described by Baillon et al.

Therefore the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment necessitated this new ground of rejection, the rejection is made **FINAL**.

Conclusion

No claims are allowed in this application. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Primary Examiner, Art Unit 1623
11/24/2010